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| <b>FORM PTO-1449 U.S. Department of Commerce</b><br>Patent and Trademark Office |  |  |  | Attorney Docket Number<br>9233-63 |  | Serial No.<br>09/873,797 |  |
| LIST OF DOCUMENTS CITED BY APPLICANT<br>(Use several sheets if necessary)       |  |  |  |                                   |  |                          |  |
| Applicants:<br>Ekwuribe et al.  |  |  |  |                                   |  |                          |  |
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| FOREIGN PATENT DOCUMENTS   |     |  |          |               |       |          |                         |
|--|-----|--|----------|---------------|-------|----------|-------------------------|
|  |     | Document Number  | Date     | Country       | Class | Subclass | Translation<br>Yes   No |
| ✓  | 1.  | GB 1 492 997   | 11/23/77 | Great Britain |       |          |                         |
| ✓  | 2.  | EP 0 031 567   | 07/08/81 | EPO           |       |          |                         |
| ✓  | 3.  | JP 1 254 699   | 10/11/89 | Japan         |       |          |                         |
| ✓  | 4.  | 0511903  | 04/23/92 | EP            |       |          |                         |
| ✓  | 5.  | 0483465B1  | 05/06/92 | EPO           |       |          |                         |
| ✓  | 6.  | WO93/01802   | 02/04/93 | PCT           |       |          |                         |
| ✓  | 7.  | WO95/09831   | 04/13/95 | PCT           |       |          |                         |
| ✓  | 8.  | EP 0 483 465   | 08/02/95 | EP            |       |          |                         |
| ✓  | 9.  | WO95/30641   | 11/16/95 | PCT           |       |          |                         |
| ✓  | 10. | EP 0 597 007   | 10/16/96 | EP            |       |          |                         |
| ✓  | 11. | EP 0 621 777   | 11/09/96 | EP            |       |          |                         |
| ✓  | 12. | EP0797615B1  | 01/10/97 | EPO           |       |          |                         |
| ✓  | 13. | WO98/07745   | 02/26/98 | PCT           |       |          |                         |
| ✓  | 14. | WO99/32134   | 07/01/99 | PCT           |       |          |                         |
| ✓  | 15. | WO99/65941   | 12/23/99 | PCT           |       |          |                         |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) |     |  |          |               |       |          |                         |
| ✓  | 16. | Abuchowski, A. and F. F. Davis "Soluble Polymer-Enzyme Adducts" pp. 367-383, <i>Enzymes as Drugs</i> , Ed. S. Holcenberg, John Wiley (1981) ✓  |          |               |       |          |                         |
| ✓  | 17. | Agarwal et al. "Polymethacrylate-based Microparticulates of Insulin for Oral Delivery: Preparation and In Vitro Dissolution Stability in the Presence of Enzyme Inhibitors" <i>International Journal of Pharmaceutics</i> 225:31-39 (2001) ✓ |          |               |       |          |                         |
| ✓  | 18. | Akiyama et al. "The Synthesis of New Derivatives of 1-β-D-Arabinofuranosylcytosine" <i>Chem. Pharm. Bull.</i> 26(3):981-984 (1978) ✓   |          |               |       |          |                         |
| ✓  | 19. | Allaudeen et al. "Orally Active Insulin: A Single Insulin Conjugate Selected for Future Studies" 60th Annual Meeting of the American Diabetes Assoc., Atlanta, GA, June 2000 (Abstract) ✓  |          |               |       |          |                         |
| ✓  | 20. | Anderson et al. "HIM2, a Novel Modified Insulin, has Improved Systemic Pharmacokinetics in Normal Dogs, Compared to Unmodified Insulin" American Diabetes Association 62nd Annual Meeting, June 2002 (Abstract) ✓                            |          |               |       |          |                         |

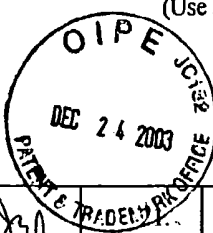
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| 22.   | Ansell et al. "Application of Oligo-(14-amino-3,6,9,12-tetraoxatetradecanoic acid) Lipid Conjugates as Steric Barrier Molecules in Liposomal Formulations" <i>Bioconjugate Chem.</i> 10:653-666 (1999) ••  |                                   |                          |
| 23.   | Aoshima et al. "N <sup>4</sup> -Behenoyl-1-β-D-Arabinofuranosylcytosine as a Potential New Antitumor Agent" <i>Cancer Research</i> 37:2481-2486 (1977) ••  |                                   |                          |
| 24.   | Baker, D. C. et al. "Prodrugs of 9-β-D-Arabinofuranosyladenine. 1. Synthesis and Evaluation of Some 5'-(O-Acyl) Derivatives" <i>J. Med. Chem.</i> 21(12):1218-1221 (1978) ••   |                                   |                          |
| 25.   | Banting et al. "Pancreatic Extracts in the Treatment of Diabetes Mellitus: Preliminary Report" <i>Can. Med. Assoc. J.</i> 145(10):1281-1286 (1991) ••  |                                   |                          |
| 26.   | Baudys et al. "Stabilization and Intestinal Absorption of Human Calcitonin" <i>J. Contr. Rel.</i> 39:145-51 (1996)   |                                   |                          |
| 27.   | Baudys et al. "Synthesis and Characterization of Different Glycosylated Derivatives of Insulin" <i>Proceed. Intern. Symp. Cont. Rel. Bioactive. Mater.</i> 19:210-211 (1992) •   |                                   |                          |
| 28.   | Block, Lawrence H. "Pharmaceutical Emulsions and Microemulsions" <i>Pharmaceutical Dosage Forms: Disperse Systems</i> Vol. 2, Ed. Lieberman et al., pp.47-109 (1996) •   |                                   |                          |
| 29.   | Boccu et al. "Pharmacokinetic Properties of Polyethylene Glycol Derivatized Superoxide Dismutase" <i>Pharm. Res. Comm.</i> 14:113-120 (1982) ••  |                                   |                          |
| 30.   | Bone et al. "Successful Treatment of an Insulin Dependent Rat Model of Human Type I Diabetes with Oral Active Insulin" Program and Abstracts, 4th International Workshop on Lessons from Animal Diabetes, Omiya, Japan, November 1994 (Abstract) •           |                                   |                          |
| 31.   | Bone et al. "Successful Treatment of Type I Diabetes with Orally-Active Insulin: Studies in The Insulin Dependent BB/S Rat" Program and Abstracts, 55th Annual Meeting of the American Diabetes Association, Atlanta Georgia, June 1995 (Abstract) •         |                                   |                          |
| 32.   | Brange and Volund "Insulin Analogs with Improved Pharmacokinetic Profiles" <i>Advanced Drug Delivery Reviews</i> 35:307-335 (1999) •   |                                   |                          |
| 33.   | Brange et al. "Chemical Stability of Insulin. 1. Hydrolytic Degradation During Storage of Pharmaceutical Preparations" <i>Pharm. Res.</i> 9(6):715-726 (1992) ••   |                                   |                          |
| 34.   | Brange et al. "Chemical Stability of Insulin. 2. Formation of Higher Molecular Weight Transformation Products During Storage of Pharmaceutical Preparations" <i>Pharm. Res.</i> 9(6):727-734 (1992) ••   |                                   |                          |
| 35.   | Brange, J. "Galenics of Insulin: The Physico-Chemical and Pharmaceutical Aspects of Insulin and Insulin Preparations" Novo Research Institute, Denmark, pp. 18-100 (1987) ••   |                                   |                          |
| 36.   | Chien, Y. W., Novel Drug Delivery Systems, pp. 678-679, Marcell Deffer, Inc., New York, N.Y. (1992)  |                                   |                          |
| 37.   | Cleland et al. "Emerging Protein Delivery Methods" <i>Current Opinion in Biotechnology</i> 12:212-219 (2001) ••  |                                   |                          |
| 38.   | Clement et al. "Effects of Multiple Doses of Orally Administered Hexyl Insulin M2 (HIM2) on Postprandial Blood Glucose (PPG) Concentrations in Type 1 Diabetic (T1) Patients" American Diabetes Association 62nd Annual Meeting, June 2002 (Poster) •        |                                   |                          |
| 39.   | Clement et al. "Oral Insulin Product Hexyl-Insulin Monoconjugate 2 (HIM2) in Type 1 Diabetes Mellitus: The Glucose Stabilization Effects of HIM2" <i>Diabetes Technology &amp; Therapeutics</i> 4(4):459-466 (2002) •  |                                   |                          |
|   | Clement, Stephen "A Dose-Escalation Study of the Effects of Two Sequential Doses of Oral Modified Insulin on Blood Glucose Concentrations in Patients with Type 1 Diabetes Mellitus" American Diabetes Association Annual Meeting (June 25, 2001) (Abstract) |                                   |                          |

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| 40.   | Clement, Stephen "A Dose-Escalation Study of the Effects of Two Sequential Doses of Oral Modified Insulin on Blood Glucose Concentrations in Patients with Type 1 Diabetes Mellitus" American Diabetes Association Annual Meeting (June 25, 2001) (Poster) |                                   |                          |
| 41.   | Conradi et al. "The Influence of Peptide Structure on Transport Across Caco-2 Cells" <i>Pharm. Res.</i> 8(12):1453-1459 (1991) ••  |                                   |                          |
| 42.   | Coombes et al. "Biodegradable Polymeric Microparticles for Drug Delivery and Vaccine Formulation: the Surface Attachment of Hydrophilic Species Using the Concept of Poly(Ethylene Glycol) Anchoring Segments" <i>Biomaterials</i> 18:1153-1161 (1997) ••  |                                   |                          |
| 43.   | Dange et al. "Poly(alkyl cyanoacrylate) Nanospheres for Oral Administration of Insulin" <i>Journal of Pharmaceutical Sciences</i> 86(12):1403-1409 (Dec. 1997) •   |                                   |                          |
| 44.   | Dandona et al. "Effect of an Oral Modified Insulin on Blood Glucose Levels in Fasting and Fed Type 1 Diabetic Patients Receiving a 'Basal' Regimen of Injected Insulin" American Diabetes Association Annual Meeting (June 25, 2001) (Abstract) •          |                                   |                          |
| 45.   | Delgado et al. "The Uses and Properties of PEG-Linked Proteins" <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> 9(3,4):249-304 (1992)  |                                   |                          |
| 46.   | Ekwuribe et al. <i>Calcitonin Drug-Oligomer Conjugates, and Uses Thereof</i> , U.S. Serial No. 10/166,355, filed 11/08/2002, including Preliminary Amendment dated 02/26/2003 and Supplemental Preliminary Amendment dated 03/31/2003 •                    |                                   |                          |
| 47.   | Ekwuribe et al. <i>Mixtures of Drug-Oligomer Conjugates Comprising Polyalkylene Glycol, Uses Thereof, and Methods of Making Same</i> , U.S. Serial No. 09/873,797, filed 06/04/2001 •  |                                   |                          |
| 48.   | Ekwuribe, Nnochiri "Conjugation-Stabilized Polypeptide Compositions, Therapeutic Delivery and Diagnostic Formulations Comprising Same, and Method of Making and Using the Same" <i>Biotechnology Advances</i> 14(4):575-576 (1996) (Abstract) •            |                                   |                          |
| 49.   | Engel et al. "Insulin: Intestinal Absorption as Water-in-Oil-in-Water Emulsions" <i>Nature</i> 219:856-857 (1968) ••   |                                   |                          |
| 50.   | Fasano, Alessio "Innovative strategies for the oral delivery of drugs and peptides" <i>TIBTECH</i> 16:152-157 (1998) ••  |                                   |                          |
| 51.   | Forst et al. "New Aspects on Biological Activity of C-peptide in IDDM Patients" <i>Exp. Clin. Endocrinol. Diabetes</i> 106:270-276 (1998) •  |                                   |                          |
| 52.   | Gish et al. "Nucleic Acids. 11. Synthesis of 5'-Esters of 1-β-D-Arabinofuranosylcytosine Possessing Antileukemic and Immunosuppressive Activity" <i>J. Med. Chem.</i> 14(12):1159-1162 (1971)  |                                   |                          |
| 53.   | Gombotz & Pettit "Biodegradable Polymers for Protein and Peptide Drug Delivery" <i>Bioconjugate Chem.</i> 6:332-351 (1995) ••  |                                   |                          |
| 54.   | Hashimoto et al. "Synthesis of Palmitoyl Derivatives of Insulin and Their Biological Activities" <i>Pharmaceutical Research</i> 6(2):171-176 (1989) ••   |                                   |                          |
| 55.   | Hinds et al. "Synthesis and Characterization of Poly(ethylene glycol)-Insulin Conjugates" <i>Bioconjugate Chem.</i> 11:195-201 (2000) •• <i>simplex</i>  |                                   |                          |
| 56.   | Hong et al. "Nucleoside Conjugates. 7. Synthesis and Antitumor Activity of 1-β-D-Arabinofuranosylcytosine Conjugates of Ether Lipids" <i>J. Med. Chem.</i> 29:2038-2044 (1986) ••  |                                   |                          |
| 57.   | Hostetler et al. "Synthesis and Antiretroviral Activity of Phospholipid Analogs of Azidothymidine and Other Antiviral Nucleosides" <i>The Journal of Biological Chemistry</i> 265(11):6112-6117 (1990) ••  |                                   |                          |

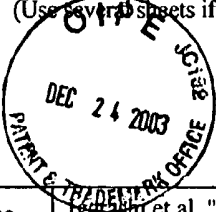
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| 58.   | Iguchi et al. "Biologically Active Peptides Conjugated with Lecithin for DDS" <i>Proceed. Intern. Symp. Cont. Rel. Bioactiv. Mater.</i> 17:367-368 (1990) /   |                                   |                          |
| 59.   | Kemmler et al. "On the Nature and Subcellular Localization of the Proinsulin Converting Enzymes" <i>Federation Proceedings</i> 30(Abstract 924):1210Abs (1971) /  |                                   |                          |
| 60.   | Kemmler et al. "Studies on the Conversion of Proinsulin to Insulin: I. Conversion in Vitro with Trypsin and Carboxypeptidase B" <i>The Journal of Biological Chemistry</i> 246(22):6786-6791 (1971) /                                   |                                   |                          |
| 61.   | King et al. "Preparation of Protein Conjugates with Alkoxypolyethylene Glycols" <i>Int. J. Peptide Protein Res.</i> 16:147-155 (1980) /   |                                   |                          |
| 62.   | Kipnes et al. "Control of Postprandial Plasma Glucose by an Oral Insulin Product (HIM2) in Patients with Type 2 Diabetes" <i>Emerging Treatments and Technologies</i> 26:2 (2003) /   |                                   |                          |
| 63.   | Kipnes et al. "The Effects of an Oral Modified Insulin on Postprandial Blood Glucose Levels in Patients with Type 2 Diabetes Mellitus" <i>American Diabetes Association Annual Meeting (June 2001) (Poster)</i> /                       |                                   |                          |
| 64.   | Kipnes et al. "The Effects of an Oral Modified Insulin on Postprandial Blood Glucose Levels in Patients with Type 2 Diabetes" <i>American Diabetes Association Annual Meeting (June 24, 2001) (Abstract)</i> /                          |                                   |                          |
| 65.   | Kube, D.M. "Multitalented Proteins Play a Key Role in Therapeutics" <i>Genomics and Proteomics</i> (Sept. 2002) /   |                                   |                          |
| 66.   | Maislos et al. "The Source of the Circulating Aggregate of Insulin in Type I Diabetic Patients is Therapeutic Insulin" <i>J. Clin. Invest.</i> 77:717-723 (1986) /  |                                   |                          |
| 67.   | Savva & Huang "Effect of PEG Homopolymer and Grafted Amphiphilic PEG-Palmityl on the Thermotropic Phase Behavior of 1,2-Dipalmitoyl-SN-Glycero-3-Phosphocholine Bilayer" <i>Journal of Liposome Research</i> 9(3):357-365 (1999) /      |                                   |                          |
| 68.   | Marschutz et al. "Oral Peptide Drug Delivery: Polymer-Inhibitor Conjugates Protecting Insulin from Enzymatic Degradation In Vitro" <i>Biomaterials</i> 21:1499-1507 (2000) /  |                                   |                          |
| 69.   | Musabayane et al. "Orally Administered, Insulin-Loaded Amidated Pectin Hydrogel Beads Sustain Plasma Concentrations of Insulin in Streptozotocin-Diabetic Rats" <i>Journal of Endocrinology</i> 164:1-6 (2000) /                        |                                   |                          |
| 70.   | Nucci et al. "The Therapeutic Value of Poly(ethylene Glycol)-Modified Proteins" <i>Ad. Drug. Del. Rev.</i> 6:133-151 (1991) /   |                                   |                          |
| 71.   | Oka et al. "Enhanced Intestinal Absorption of a Hydrophobic Polymer-Conjugated Protein Drug, Smancs, in an Oily Formulation" <i>Pharm. Res.</i> 7(8):852-855 (1990) /   |                                   |                          |
| 72.   | Pang, David C. "Bridging Gaps in Drug Discovery and Development" <i>Pharmaceutical Technology</i> 22:82-94 (Nov. 1998) /  |                                   |                          |
| 73.   | Patel et al. "Oral Administration of Insulin By Encapsulation Within Liposomes" <i>FEBS Lett.</i> 62(1):60-63 (1976) /  |                                   |                          |
| 74.   | Price, JC <i>Polyethylene Glycol</i> , pp. 355-361 (not dated)  |                                   |                          |
| 75.   | Puskas et al. "Investigation of Chymotrypsin Digestion Profile of Orally Active Insulin Conjugate HIM2" <i>AAPS Pharm Sci.</i> 3(3) 2001 (Abstract) /   |                                   |                          |
| 76.   | Radhakrishnan et al. "Chemical Modification of Insulin with Amphiphilic Polymers Improves Intestinal Delivery," <i>Proceed. Intl. Symp. Control. Rel. Bioact. Mater.</i> 25:124-125 (1998) (Abstract) /                                 |                                   |                          |
| 77.   | Radhakrishnan et al. "Oral Delivery of Insulin: Single Selective Modification at B29-LYS With Amphiphilic Oligomer" Program and Abstracts, 1999 National Meeting of the Ameri. Assoc. Pharm. Scient., New Orleans, LA (1999) (Abstract) |                                   |                          |

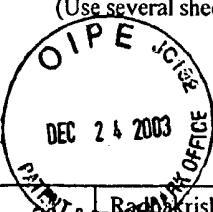
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|  | 78. Radhakrishnan et al. "Structure-Activity Relationship of Insulin Modified with Amphiphilic Polymers" Program and Abstracts, 1998 National Meeting of the Amer. Assoc. Pharm. Scient., San Francisco, CA <i>Pharm. Sci.</i> 1(1):S-59 (1998) (Abstract) |                                   |                          |
| 79.   | Radhakrishnan et al. <i>Insulin Polypeptide-Oligomer Conjugates, Proinsulin Polypeptide-Oligomer Conjugates and Methods of Synthesizing Same</i> , U.S. Serial No. 10/389,499, filed 03/17/2003  |                                   |                          |
| 80.   | Ratner, R. E. et al. "Persistent Cutaneous Insulin Allergy Resulting from High-Molecular Weight Insulin Aggregates" <i>Diabetes</i> 39:728-733 (1990)  |                                   |                          |
| 81.   | Richards et al. "Self-Association Properties of Monomeric Insulin Analogs Under Formulation Conditions" <i>Pharmaceutical Research</i> 15(9):1434-1441 (1998)  |                                   |                          |
| 82.   | Robbins et al. "Antibodies to Covalent Aggregates of Insulin in Blood of Insulin-Using Diabetic Patients" <i>Diabetes</i> 36:838-841 (1987)  |                                   |                          |
| 83.   | Russell-Jones, G. J. "Vitamin B12 Drug Delivery" <i>Proceed. Intern. Symp. Control. Rel. Bioactive. Mater.</i> 19:102-103 (1992)   |                                   |                          |
| 84.   | Saffran et al. "A Model for the Study of the Oral Administration of Peptide Hormones" <i>Can J Biochem</i> 57:548-553 (1979)   |                                   |                          |
| 85.   | Saffran, M. et al. "A New Approach to the Oral Administration of Insulin and Other Peptide Drugs" <i>Science</i> 233:1081-1084 (1986)  |                                   |                          |
| 86.   | Santiago et al. "Oral Immunization of Rats with Influenza Virus M Protein (M1) Microspheres" <i>Proceed. Intern. Symp. Cont. Rel. Bioactive. Mater.</i> 19:116-117 (1992)  |                                   |                          |
| 87.   | Shah and Shen "Transcellular Delivery of an Insulin-Transferrin Conjugate in Enterocyte-like Caco-2 Cells" <i>Journal of Pharmaceutical Sciences</i> 85(12):1306-1311 (1996)   |                                   |                          |
| 88.   | Shichiri et al. "Enteral Absorption of Water-in-Oil-in-Water Insulin Emulsions in Rabbits" <i>Diabetologia</i> 10:317-321 (1974)   |                                   |                          |
| 89.   | Soltero et al. <i>Insulin Polypeptide-Oligomer Conjugates, Proinsulin Polypeptide-Oligomer Conjugates and Methods of Synthesizing Same</i> U.S. Serial No. 10/382,022, filed 03/05/2003  |                                   |                          |
| 90.   | Soltero et al. <i>Pharmaceutical Compositions of Drug-Oligomer Conjugates and Methods of Treating Diseases Therewith</i> U.S. Serial No. 10/382,069, filed 03/05/2003  |                                   |                          |
| 91.   | Soltero et al. <i>Pharmaceutical Compositions of Insulin Drug-Oligomer Conjugates and Methods of Treating Diseases Therewith</i> U.S. Serial No. 10/382,155, filed 03/05/2003  |                                   |                          |
| 92.   | Still and McAllister "Effects of Orally Active Modified Insulin in Type 1 Diabetic Patients" <i>Clinical Pharmacol. Therap.</i> 69(2):P95 (Feb. 2001) (Abstract)   |                                   |                          |
| 93.   | Still and McAllister "Effects of Orally Active Modified Insulin in Type I Diabetic Patients" Slide Presentation Annual Meeting of the American Society for Clinical Pharmacology & Therapeutics, Orlando, FL, March 9, 2001                                |                                   |                          |
| 94.   | Still and McAllister "Effects of Orally Active Modified Insulin in Type I Diabetic Patients" Annual Meeting of the American Society for Clinical Pharmacology & Therapeutics, Orlando, FL, March 9, 2001 (Handout)   |                                   |                          |
| 95.   | Still et al. "Magnitude and Variability of Pharmacokinetic and Glucodynamic Responses to Modified Human Insulin Administered Orally to Healthy Volunteers" <i>Diabetes Research and Clinical Practice</i> 56:S77 (2002)                                    |                                   |                          |
| 96.   | Still et al. <i>Methods of Reducing Hypoglycemic Episodes in the Treatment of Diabetes Mellitus</i> , U.S. Serial No. 10/461,199, filed 06/13/2003   |                                   |                          |

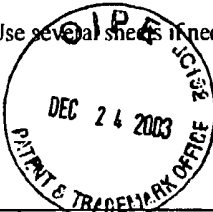
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| 97.   | Still, J. Gordon "Development of Oral Insulin: Progress and Current Status" <i>Diabetes/Metabolism Research and Reviews</i> 18(1):S29-S37 (2002)  |                                   |                          |
| 98.   | Still, J. Gordon "Oral Insulin Development" Slide Presentation, VI International St. Barts Symposium Diabetes 2000: Therapy and Technology, London, England, May 12, 2000   |                                   |                          |
| 99.   | Szleifer et al. "Spontaneous Liposome Formation Induced by Grafted Poly(Ethylene Oxide) Layers: Theoretical Prediction and Experimental Verification" <i>Proceedings of the National Academy of Sciences of the United States of America</i> 95(3):1032-1037 (1998) |                                   |                          |
| 100.  | Taniguchi et al. "Synthesis of Acyloyl Lysozyme and Improvement of its Lymphatic Transport Following Small Intestinal Administration in Rats" <i>Proceed. Intern. Symp. Control. Rel. Bioactiv. Mater.</i> 19:104-105 (1992)  |                                   |                          |
| 101.  | Uchio et al. "Site-Specific Insulin Conjugates with Enhanced Stability and Extended Action Profile" <i>Advanced Drug Delivery Reviews</i> 35:289-306 (1999)   |                                   |                          |
| 102.  | Wahren et al. "Role of C-peptide in Human Physiology" <i>Am. J. Physiol. Endocrinol. Metab.</i> 278:E759-E768 (2000)  |                                   |                          |
| 103.  | Zalipsky et al. "Attachment of Drugs to Polyethylene Glycols" <i>Eur. Polym. J.</i> 19(12):1177-1183 (1983)   |                                   |                          |
| 104.  | Ziv and Bendayan "Intestinal Absorption of Peptides Through the Enterocytes" <i>Microscopy Research and Technique</i> 49:346-352 (2000)   |                                   |                          |

EXAMINER  
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*Jeffrey E. Duvall*

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*August 18, 2004*

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